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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,801	10/25/2000	Lee A. Bulla JR.	48279-3U\$PT	3203

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EXAMINER
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CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/22/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/696,801	BULLA ET AL.
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 February 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 13-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-82 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) All b) Some \* c) None of:  
        1. Certified copies of the priority documents have been received.  
        2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
        3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7 and 9</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

Applicant's election with traverse of claims 34-82 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the claims in groups III-VI are all drawn to the same invention, including the method, system, computer program and computer readable media. The arguments have been deemed persuasive and therefore the requirement for these claims has been cancelled.

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11

### ***Specification Objection***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (for example: see page 6). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claims Rejections-35 USC 101***

Claims 13-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Although one could argue that the method for targeting gene sequences could be useful in further research to identify potentially homologous gene sequences, there is no specificity identified as to what types of sequences are being analyzed. Therefore, the invention does not meet the standard of being immediately useful. The need to do extensive work after generating the sequences does not meet the "concrete, tangible, and useful" result standard set forth in MPEP 2106.

MPEP 2106: “For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing O’Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible, and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible, and useful. See AT&T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible, and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and /or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc).”

***Claims Rejections-35 USC 112***

Claims 13, 14, 21-23, 34-36, 43- 45, 56-61, 68-70, and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following recitations are unclear:

In claim 13 and respective claims what are the important “phenotypic” characteristics?

The process of “selecting one or more gene sequence” is unclear. From where are the gene sequences being selected? Are the groups being selected for sequence similarity, motif, 3-D structure or any other criteria?

What is the process of “extracting a catalogued gene sequence” and what portions are being extracted? The gene sequence could be from Genbank or EMBL or any other of the numerous databases.

How is “prioritization of the extracted sequence” accomplished? Does this mean extracting the closest matches? What is the basis of priority? This could mean that the sequences with the closest actual matches are used or the sequences with the closest pattern match.

How is the “filtering” in claim 14 and respective claims done? Is this accomplished by using existing algorithms in BLAST or other search systems?

In claim 21 and respective claims, how do the preceding claims relate to “biopesticide encoding genes”? Which biopesticides?

In claim 22 and respective claims, how do the preceding claims relate to “therapeutic encoding genes”? Which therapeutic encoding genes for what specific therapy?

In claim 23 and respective claims which statistical analyses are utilized? There are a number of ways to analyze data, including the simple student T-test or other, more complicated, means.

In claim 56, what is the definition of “high specificity primer selection”? How good does the match have to be?

In claim 57, what is meant by “high specificity positioning”? Again, how high is high? Could there be a one base pair difference or two or more?

In claim 68, what are the “target molecules”? Are they the molecules of interest? Are they known molecules?

***Claims Rejections-35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13, 14, 16, 20, 21-30, 32-36, 38, 42-52, 54-61, 63, 67-77, and 79-82 are rejected under 35 U.S.C. 102(e) as being anticipated by Messier et al (US 6,274,319). Messier teaches methods for identifying polynucleotide and polypeptide sequences having evolutionarily significant changes (column 4, lines 9-11). Specifically, in claim 13 and respective claims, the method of selecting one or more phenotypic characteristic, selecting a sequence known to have that characteristic, selecting database(s) containing catalogued gene sequences, extracting relevant gene sequences, aligning the sequences, and designing primers is described in column 5, paragraph 1 and 2; column 6, paragraph 2 and 3; column 9, paragraph 4; column 10, paragraph 3;

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and column 11, paragraph 3. Messier et al. teach the limitations of claim 14 and respective claims in column 11, paragraph 3, which describes the process of BLAST alignments, which include filtering of sequences. Claim 16 and respective claims are taught in column 10, paragraph 3, which teaches generation of primers based upon ancestral cDNA, which implies the use of degenerate primers. Claim 20 and respective claims are anticipated by Messier et al., who teach the use of primers to clone a target molecule (column 10, paragraph 3). Claims 21, 22 and respective claims are anticipated by column 15, paragraph 6 which describes the identification of “agents” that are useful in modulating organisms. For instance, agents can be compounds connected with therapies or expression alteration, which could include biopesticides for plants and therapies for animals. BLAST, a local alignment search tool, as well as CLUSTAL W, are used, anticipating claim 24 and respective claims. Furthermore, BLAST, as well this reference includes analysis of amino acid sequence, nucleic acid sequence, genomic DNA, open reading frames, introns and exons, meeting the limitations of claims 25-30 and respective claims (see column 6, paragraph 2 and column 9, paragraph 7). Messier et al. teach the use of this method for domesticated animals and plants, meeting the limitations of claims 32, 33 and respective claims.

Claims 13-15, 17, 18, and 23-37, 39, 40 , 45-55, 57, 60-62, 64, 65, and 70-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Sabatini et al. (US 5,966,712). Sabatini et al. disclose a database for storing and manipulating biomolecular sequence information from genomic libraries for a plurality of organism types (see abstract).

Sabatini et al. specifically teach selecting a characteristic of a sequence (i.e. genomic complement, ORF etc.) from a variety of sources, comparing the sequences to those in a

database, aligning selected sequences, ranking according to matches, and targeting sequences via electronic Southern analysis (columns 5-30). Furthermore, the invention covers databases optimized for many types of sequence data, including those from human, primate, rodent, amphibian, insect etc., thus meeting the limitations of claims 13-15, 17, 18, and 23-33 and respective claims which encompass the computer program and system.

No claim is allowed.

*Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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April 17, 20020

Lori A. Clow, Ph.D.

Art Unit 1631

*Lori A. Clow*

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MARY K. ZEMAN  
PRIMARY EXAMINER

*AV(631)*